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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/692,401	10/19/2000	Leonora Heidecker	L0461/7097-(JRV)	7318

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EXAMINER

DECLoux, AMY M

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 12/07/2001

13

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/692,401

Applicant(s)

Heldecker et al

Examiner

DeCloux, Amy

Art Unit

1644



-- Th MAILING DATE of this communication appears on th cover sh t with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1) ☒ Responsive to communication(s) filed on Oct 2, 2001

2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

## Disposition of Claims

4) ☒ Claim(s) 1-4, 7, 8, 10, 16, 18-20, 34, 40-44, 46, 52, and 53 is/are pending in the applica

4a) Of the above, claim(s) 10, 16, 18-20, 34, 40, 41, 44, 46, 52, and 53 is/are withdrawn from considera

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☒ Claim(s) 1-4, 7, 8, 42, and 43 is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirem

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some\* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 12
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

Note: The examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Amy DeCloux, Group Art Unit 1644, Group 1640, Technology Center 1600.

1. Applicant's amendment, filed 10/5/01 (Paper No. 11), is acknowledged.
2. The rejections of record can be found in the previous Office Action, mailed 7-3-01 (Paper No. 10).

In view of applicant's amendment and remarks, filed 10/5/01, the 112 first written description rejection as applied to claim 3 has been withdrawn, as have the 112 second paragraph rejections and the 103(a) rejections. However, the 112 first written description rejection as applied to claims 1-2, 4, 7-8 and 42-43 and the 112 first enablement rejection 1-4, 7-8 and 42-43 has been maintained essentially for the reasons of record. Also a new grounds of rejection (112 second paragraph) has been applied to newly amended claim 1 and its dependent claims 2-4, 7-8 and 42-43.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. MAINTAINED Claims 1-2, 4, 7-8 and 42-43 are rejected under 35 USC 112, first paragraph as containing subject matter which was not described in the specification in such a way to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicant traverses the rejection on the grounds that the rejection is not in agreement with the written description examination guidelines and should be withdrawn. Applicants assert that instant claim 1 which recites, in part, "An isolated MAGE-A12 HLA class I-binding peptide comprising the amino acid sequence of SEQ ID NO:6.." is completely analogous to claim 1 of Example 13 of said guidelines. Applicant also points out that regarding said exemplary claim, the training materials stated that there is relatively little variation among the species within the genus because each member of the genus shares SEQ ID NO:3 as a necessary common feature. However the examiner notes that said training materials state that said exemplary SEQ ID NO:3 translates into a 65KD protein, which is significantly different in size than the class I-binding peptides which are about 8-10 amino acids in length or about 1.5 KD. The

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examiner notes that the instant claims encompass a peptide comprising a specific amino acid sequence or a functional variant or a fragment hereof. As noted in the previous office action, the open language (comprising) of the instant claims, the recited peptide/variants/fragments and vaccine thereof, can comprise amino acids that flank the sequences of recited SEQ ID Nos in the protein of origin, or can be any number of undisclosed and unrelated sequences. Therefore, the little variation of sequences described in Example 13 of said guidelines which describes a genus of sequences comprising an amino acid sequence of 65KD, is very different from the large variation of sequences encompassed by the instant claims which encompass sequences comprising an amino acid sequence of about 1.5 KD and fragments, variants thereof and vaccines or compositions thereof.

The examiner notes that by limiting the variants to those having one amino acid difference from the recited sequence overcomes the rejection with regard to claims encompassing peptides with closed language, such as claim 3.

Therefore, though applicant's arguments have been carefully considered, they are not deemed persuasive, and the rejection is maintained, essentially for the reasons of record.

5. MAINTAINED Claims 1-4, 7-8 and 42-43 are rejected under 35 USC 112, first paragraph, because the specification, while being enabled for an isolated MAGE-A12 HLA class I binding peptide consisting of SEQ ID NO:4, 5 or 6, and said sequences with one amino acid addition substitution or deletion, does not reasonably provide enablement for making and/or using the claimed isolated MAGE-A12 HLA class I binding peptide: (1) which is a functional variant of SEQ ID NO:6, nor (2) which is a functional variant or fragment of SEQ ID NO:4 or 5, (3) a composition, including a vaccine composition, comprising any one of (1) or (2), other than SEQ ID NO:6 which is a fragment of SEQ ID NO:4 and 5, and SEQ ID NO:4 which is a fragment of SEQ ID NO:5. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants traverse the rejection on the grounds that the examiner considered only two of the Wands factors (amount of guidance and the quantity of experimentation) in making the rejection, and that full consideration of each and all of the Wands factors would lead one to the conclusion that practicing the invention as claimed would not require undue experimentation. The examiner notes that the Factors to be considered in determining whether undue experimentation is required are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, unpredictability in the art, the amount of experimentation required, and the amount of direction or guidance presented, all of which were considered in said rejection in the previous office action.

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Applicants contend that guidance for the preparation and testing of variant peptides is disclosed. While the examiner agrees this is true for peptides consisting of SEQ ID NO:3, 4, 5 and 6, and for said sequences with one amino acid addition substitution or deletion, the examiner contends that there is insufficient guidance and direction in the instant specification regarding making any peptide comprising SEQ ID NO:3, 4, 5 and 6, or a fragment thereof, and that there is insufficient guidance and direction in the instant specification in predicting which peptides comprising SEQ ID NO:3, 4, 5 and 6, or a fragment thereof would display the recited properties, especially given the breadth of said claims, the limited disclosed working examples and the teachings of Englehard and of Guo regarding peptide binding to MHC Class I molecules. Said teachings reflect the state of the prior art and the level of one of ordinary skill in the art, and said teachings are used to assess the nature of the instant invention as detailed in section 23 of the previous office action.

Therefore, though applicant's arguments have been carefully considered, they are not deemed persuasive, and the rejection is maintained, essentially for the reasons of record.

#### NEW GROUNDS OF REJECTION

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.

7. Claim 1 and dependent claims 2-4, 7-8 and 42-43 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claim 1 and dependent claims 2-4, 7-8 and 42-43 are indefinite in the recitation of "substitutions" in line 3 of claim 1 because of the adjective "one". Substituting "substitution" would overcome this rejection.

8. No claim is allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of


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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.  
Patent Examiner,  
Group 1640, Technology Center 1600  
December 5, 2001

  
DAVID SAUNDERS  
PRIMARY EXAMINER  
ART UNIT 182/644